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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/571,600

07/05/2006

Ahd Hamidi

2001-1437

9771

466

7590

07/10/2007

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EXAMINER

ARCHIE, NINA

ART UNIT

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1645

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07/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/571,600 | Applicant(s) HAMIDI ET AL. | |
| | Examiner Nina A. Archie | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/10/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

3. The information disclosure statement filed on 3/10/2006 has been considered. An initialed copy is enclosed.

Election/Restrictions

4. Applicant's election without traverse of Group II claims 6-8 and 19 are acknowledged.

Claim Objections

5. Claim 6 is objected to because of the following informalities: As to claim 6, an independent claim, recitation "chromatography,;" (misplaced comma). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6-8 and 19 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The claim is drawn to a method for recovering a polysaccharide from a fermentation broth comprising: omitting the use of centrifugation, ultracentrifugation and chromatography; maximally 4 precipitation steps. Critical or essential subject matter to the practice of the invention is not included in claim 6 and therefore is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). For example the precipitation steps are not described therefore the method steps are unclear of how to recover a polysaccharide from a fermentation broth. Furthermore, claim 6 recites "chromatography", as to the limitation of chromatography, there are multiple forms of chromatography therefore it is unclear as to which chromatography method Applicant is referring to.

7. Claims 6-8 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 6 independent claim, and dependent claims 7-8 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The method step of claim 6 is not clear and Examiner is not able to interpret the method steps or how the method steps can be performed. For example it is the precipitations steps have not been described and there are multiple forms of chromatography therefore it is unclear when the precipitations steps are used in the method for recovering a polysaccharide from a fermentation broth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 6-8 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Cano et al US Patent 4,242,501 Date December 30, 1980.

Claims 6-8 and 19 are drawn to a method for recovering a polysaccharide from a fermentation broth comprising: omitting the use of centrifugation, ultracentrifugation and chromatography; maximally 4 precipitation steps.

Cano et al teach a method for recovering a polysaccharide from a fermentation broth (see Example 2). Cano et al teach a method wherein the recovery includes: a method of fermentation stopped by the addition of sodium desoxycholate (anionic detergent), with each polysaccharide being precipitated with alcohol, then following hexadecyltrimethylammonium bromide (cationic detergent) (see columns 3 lines 35-67, column 4 lines 1-67, see examples 1-13) subjecting the polysaccharide to concentration and diafiltration (see examples 1). Therefore Cano et al anticipate mixing the polysaccharide fraction with a cationic detergent (hexadecyltrimethylammonium bromide (cetavlon) adding alcohol until a concentration, which is below the concentration necessary for precipitating the polysaccharide, whereby using a cationic detergent to precipitate the polysaccharide or part of the contaminants from the supernatant to obtain a polysaccharide fraction; subjecting the second polysaccharide fraction to an alcohol precipitation in the presence of an anionic detergent, whereby using alcohol is present in a concentration which is below the concentration at which the polysaccharide precipitates; precipitating the polysaccharide from the soluble fraction using alcohol to obtain a polysaccharide precipitate; dissolving the polysaccharide precipitate and subjecting it to concentration and diafiltration, residue fraction to obtain a

second polysaccharide fraction, whereby using a cationic detergent (hexadecyltrimethylammonium bromide (cetavlon) to precipitate the polysaccharide or part of the contaminants from the supernatant to obtain a first polysaccharide fraction; using alcohol to precipitate the polysaccharide from the first polysaccharide fraction to obtain a second polysaccharide fraction; subjecting the second polysaccharide to an alcohol precipitation in the presence of an anionic detergent, whereby the alcohol is present in a concentration which is below the concentration at which the polysaccharide precipitates; precipitating the polysaccharide from the soluble fraction using alcohol to obtain a polysaccharide precipitate; dissolving the polysaccharide precipitate and subjecting it to concentration and diafiltration.

9. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al US Patent 5,316,926 Date May 31, 1994.

Claims 6-7 are drawn to a method for recovering a polysaccharide from a fermentation broth comprising: omitting the use of centrifugation, ultracentrifugation and chromatography; maximally 4 precipitation steps.

Brown et al teach a method for recovering a polysaccharide (hyaluronic acid) from a fermentation broth wherein the polysaccharide (hyaluronic acid) is precipitated and then an addition of an anionic surfactant and a cationic surfactant (hexadecyltrimethylammonium bromide) subjecting the concentration to filtration (see abstract, see column 4, column 7 lines 30-35, columns 8-10). Therefore Brown et al teach anticipate a method wherein the recovery includes: mixing the polysaccharide fraction with a cationic detergent (cationic surfactant/hexadecyltrimethylammonium bromide (cetavlon) adding alcohol until a concentration necessary for precipitating the polysaccharide.

Status of the Claims

10. Claims 6-8 and 19 are rejected.
No claims are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nina A Archie

Examiner

GAU 1645

REM 3B31



MARK NAVARRO
PRIMARY EXAMINER